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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,059	12/02/2003	Robert E. Carlson	14095.1USC6	5023

7590 11/15/2007

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EXAMINER	
SHIBUYA, MARK LANCE	
ART UNIT	**PAPER NUMBER**
1639	

MAIL DATE	DELIVERY MODE
11/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,059	CARLSON, ROBERT E.	
	Examiner	Art Unit	
	Mark L. Shibuya, Ph.D.	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *78-82,84-86 and 88-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *78-82, 84-86, 88-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/06, 6/6/07, 7/13/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Application 10/727,059, (20030203405 A1): Claims 78-82, 84-86, 88-91 are pending and examined.

Priority

2. This application, 10/727,059, filed 12/02/2003, in the application data sheet, entered 9/13/2004, states that it is a continuation-in-part of 10/244,727, filed 9/16/2002, which claims benefit of 60/360,980, filed 3/1/2002; 60/362,600, filed 3/8/2002; 60/375,655, filed 4/26/2002 and 60/400,605, filed 8/05/2002.

3. Applicant is requested to amend the first line of the specification to reflect the type of the instant application as a continuation-in-part of 10/244,727.

Withdrawn Claim Objections/Rejections

4. The following claim rejections/objections are withdrawn in view of applicant's arguments and amendments to the claims:

5. Claims 78-92 and 94-96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 78-84, 86-92 and 94-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Maly et al., Proc. Natl. Acad. Sci. USA, 3/14/2000, Vol. 97, no. 6, pp. 2419-2424 (IDS entered 12/02/2003).

7. Claims 78-84, 86-92 and 94-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Shao et al., J. Org. Chem. 1996, Vol. 61, pp. 6086-6087, (IDS entered 12/02/2003).

8. Claims 78-84, 86-92 and 94-96 are rejected under 35 U.S.C. 102(b) as being anticipated by New et al., WO 01/01140 A1, (IDS entered 8/10/2006).

9. Claims 78-84, 86-92 and 94-96 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/25910 A1, Stålberg.

Information Disclosure Statement

10. The following Information Disclosure Statements (IDS), entered on the dates that follow, have been considered: 10/12/06, 6/6/07, and 7/13/07. The publication DE 197 40 263, (IDS filed 7/13/2007), was considered to the extent that said publication is the same as US 6,875,620. The publication of WO 00/13017, (IDS filed 7/13/2007) was considered only to the extent of the English language abstract.

New Claim Rejections - 35 USC § 112, Second Paragraph

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 78-82, 84-86, 88-91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 78 states the limitation "the shape of a spot", which render the claim vague and indefinite, because the limitation is not defined by the claim, the specification does not provide a standard for ascertaining what would or not be encompassed by "the shape of a spot", and one of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte*

Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 78 recites the broad recitation "a plurality of regions", and the claim also recites "a first region" and "a second region" which is the narrower statement of the range/limitation. Thus it is unclear if there are only two regions that constitute the plurality of regions in claim 78.

Maintained Claim Rejections

13. The following rejections are maintained for the reasons of record as set forth in the previous Office action. The rejections are necessitated by applicant's amendments to the claims.

Maintained Claim Rejections - 35 USC § 102

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

15. Claims 78-82, 84, 86, 88-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Korbel et al., J. Am. Chem. Soc. 2001, 12/20/2000, Vol. 123, 361-362, (IDS entered 8/10/2006).

The claims are drawn to methods of making a heterogeneous building block array, the method comprising: applying building blocks to a solid support in a plurality of spots, the spots comprising 2, 3, 4, 5, or 6 different building blocks; independently coupling the different building blocks to the solid support in the spots, wherein one or more of the building blocks comprises one or more amino acids; and variations thereof.

Korbel et al., J. Am. Chem. Soc. 2001, Vol. 123, 361-362 (published on the web 12/20/2000), throughout the publication, disclose making an array (Figures 1 and 2) comprising various ratios of D and L amino acids, including serine, which bind in a enantiomer-specific fashion to chiral fluorescent probes (see p. 361, para 2-3, Scheme 1), reading on making a heterogeneous building block array. Korbel et al. teach automated contact printing of nanoliter volumes to spots on a glass slide in a spatially arrayed manner (p. 361, para 2), reading on pin spotting a plurality of spots on a solid support, the spots comprising 2, 3, 4, 5, or 6 different building blocks; and coupling building blocks to the solid support in the spots.

Response to Arguments

Applicant argues that none of the references teach nor suggest the claimed method of making an array.

Applicant's arguments, entered 8/30/2007, have been fully considered but they are not persuasive. Korbel et al. teach chiral fluorescent probes covalently coupled to support supports in regions. These regions have different combinations in that different ratios of d- and l- enantiomeric probes. Furthermore, Korbel et al., at p. 362, Fig. 1, teach different chiral probes for 7 different amino acids. Korbel et al., at Scheme 1, teach building blocks that meet the limitations of the amended claims.

16. Claims 78-82, 84, 86, 88-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Pirrung, Chemical Reviews, 1997, vol. 97, No. 2, pp. 473-488, (IDS entered 12/02/2003).

Pirrung, Chemical Reviews, 1997, vol. 97, No. 2, pp. 473-488, (IDS entered 12/18/2002), throughout the publication, discloses methods of making peptides on 96 microtiter well plates, wherein the amino acids of a peptide can include, for example, serine, tyrosine and threonine (p. 474, Figure 2, reading on 2 or more different, heterogeneous building blocks) that are coupled onto, e.g., microtiter wells (e.g., p. 474, Figure 1) using pin spotting, or spotted onto paper, (pp. 485-486).

Response to Arguments

Applicant argues that none of the references teach nor suggest the claimed method of making an array.

Applicant's arguments, entered 8/30/2007, have been fully considered but they are not persuasive. Pirrung, at p. 481, Figure 17, teach a plurality of building blocks in a region that are covalently coupled to the solid support.

17. Claims 78-82, 84, 86, 88-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Balch, US 6,083,763 A.

Balch, US 6,083,763 A, throughout the patent, and especially at col. 36, line 39-col. 37, line 50, Example IV, discloses methods of forming various biospecific molecules

in a well, reading on a spot as claimed, among a plurality of wells on a plate, said plate reading on a solid support. Balch, at col. 37, lines 15-47, teaches, as an example, four different haptens immobilized at different biosites within a single well; and bispecific molecules, specific for one of the said haptens and for different analytes; wherein the hapten-bispecific molecules read on 2, 3, 4, 5, or 6 different building blocks. Balch teaches bispecific ligands that comprise antibodies, which absent evidence to the contrary, would comprise amino acids serine, threonine, and tyrosine (col. 37, lines 9-15). Balch teaches, at col. 9, lines 56-60, different substrates, including glass; at col. 3, lines 44-49, pin spotting; at e.g., col. 30, lines 37-62, teaches printing activated haptens onto an amino-silanized glass surface, reading on a functionalized lawn.

Response to Arguments

Applicant argues that none of the references teach nor suggest the claimed method of making an array.

Applicant's arguments, entered 8/30/2007, have been fully considered but they are not persuasive. Balch, at col. 18, line 55, col. 21, line 24-col. 22, line 32, col. 33, lines 30-48, col. 36, line 62, teach covalent attachment of probes, reading on building block molecules, and wherein these molecules meet the new claim limitations as to structure.

18. Claims 78-82, 84-86, 88-91 are rejected under 35 U.S.C. 102(e) as being anticipated by Lahiri et al., US 20030138853 A1.

The amended claims are drawn to a method of making a heterogeneous building block array, the method comprising: applying building blocks to a solid support in a plurality of spots, each spot comprising 2, 3, 4, 5, or 6 different building blocks; independently coupling the different building blocks to the solid support in the spots; wherein a first spot comprises a first combination of building blocks and a second spot comprises a second combination of building blocks; and variations thereof.

Lahiri et al., US 20030138853 A1, throughout the publication, and especially at the abstract, describe methods of making arrays comprising a plurality of biological membrane microspots associated with a surface of a substrate, reading on heterogeneous building block array; Lahiri et al., at p. 3, right column-p. 4, left column, describe a method of making microspots comprising multiple different proteins, and Lahiri et al., at pp. 3-4, para [0039], disclose more than one type of protein in each microspot, and G-protein coupled receptors (GPCRs) heterodimers and teach a plurality of different protein on separate microspots, reading on applying building blocks to a solid support in a plurality of spots, each spot comprising at least 2 different building blocks; independently coupling the different building blocks to the solid support in the spots; wherein a first spot comprises a first combination of building blocks and a second spot comprises a second combination of building blocks. Lahiri et al., state:

> [0039] Typically, when the biological membrane microspot comprises a membrane bound protein, only one type of protein is included in each microspot of the array. However, in certain situations more than one type of protein is included in each microspot. For example, some GPCRs

> heterodimerize for their biological functions. (Angers, S. et al., Proc. Natl. Acad. Sci. USA, 2000, 97, 3684-3689.) In a preferred embodiment of the array, the protein included in the microspot differs from the protein included on a second microspot of the same array. In such an embodiment, a plurality of different proteins are present on separate microspots of the array. Typically the array comprises at least about ten different proteins. Preferably, the array comprises at least about 50 different proteins. More preferably, the array comprises at least about 100 different proteins. Alternative preferred arrays comprise more than about 10^3 different proteins or more than about 10^4 different proteins. The array may even optionally comprise more than about 10^5 different proteins.

Lahiri et al., at para [0039].

Lahiri et al., e.g., at para [0040]-[0041], further teach various numbers of microspots.

Lahiri et al., teach heteromultimers of proteins, which absent evidence to the contrary, read on recognition elements that are hydrogen bond donors and acceptors, and which proteins would inherently have, absent evidence to the contrary, positively and negatively charged recognition units, and would constitute small and bulky recognition elements).

Lahiri et al., state:

> [0040] In one embodiment of the array, each of the microspots of the array comprises a different protein. For instance, an array comprising about 100 microspots could comprise about 100 different proteins. Likewise, an array of about 10,000 microspots could comprise about 10,000 different proteins. In an alternative embodiment, however, each different protein is included on more than one separate microspot on the array. For instance, each different protein may optionally be present on two to six different microspots. An array of the invention, therefore, may comprise about three-thousand microspots, but only comprise about one thousand different proteins since each different protein is present on three different microspots.

Lahiri et al., at para [0040]. Thus Lahiri et al., teach a first spot comprising a first building block and no other, and a second building block but not other.

Lahiri et al., state:

> [0041] In a further alternative embodiment, the array comprises identical microspots or a series of identical microspots that in use are treated with a different analyte (target). For example, an array of the invention can include a "mini array" of 20 microspots, each microspot containing a different membrane bound protein, wherein the mini array is repeated 20 times as part of the larger array.

Lahiri et al., at para [0041]. Thus Lahiri et al., teach a combination of building blocks replicated in a plurality of spots.

Lahiri et al., e.g., at pp. 1-2, in the Summary of the Invention, and p. 4, right column-p. 5, left column, teach coating material reading on a functionalized lawn for coupling proteins. Lahiri at para [0063], teach pin spotting. Lahiri et al., at para [0085], teach pin spotting on to slides reading on glass plates and microscope slides.

At stated above, Lahiri et al., at para [0039], contemplate protein subunits of heteromultimeric receptors that read upon different building blocks mixed in a spot, (see Lahiri, which states: "However, in certain situations more than one type of protein is included in each microspot. For example, some GPCRs heterodimerize for their biological functions."). There were known in the art, receptors that are heterotrimers, or higher heteromultimers, as evidenced by Evans et al., US 5,990,163, at col. 4, lines 18-40, (teaching heteromultimeric retinoid receptors), so that Lahiri et al., teach methods wherein each comprising 3 or more different building blocks.

Response to Arguments

Applicant argues that none of the references teach nor suggest the claimed method of making an array.

Applicant's arguments, entered 8/30/2007, have been fully considered but they are not persuasive. Lahiri et al., at p. 1, para [0006]-p. 2, [0018], p. 3, para [0038], pp. 4-5, para [0051]-[0057], teach covalent attachment of probes, reading on building block molecules, and wherein these molecules meet the new claim limitations as to structure.

Maintained Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 78-82, 84-86, 88-91 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 85-160 of copending Application No. 10/244,727. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of making a heterogeneous building block array, comprising forming a plurality of spots on a solid support, the spots comprising 2, 3, 4, 5 or 6 different building blocks, and coupling building blocks to the solid support in the spots, as in the claims of the instant application, is anticipated by and obvious over the method of making a heterogeneous building block array, the method comprising forming a plurality of spots on a solid support, the spot comprising a plurality of building blocks; and immobilizing building blocks to the support in the spots by covalent coupling, by an ionic interaction, or by a combination thereof, as in the claims of copending Application No. 10/244,727.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that following similar claims of related applications, also are subject to the doctrine of obviousness-type double patenting: 10/813,612 (claims 1-9); 10/934,977 (claims 1-9); 11/004,593 (claims 25-32); 11/217,384 (claims 1-6); and 11/223,463 (claims 1 and 2).

The examiner respectfully requests applicant's assistance in identifying any other applications subject to double patenting over the claims of the instant application.

Response to Arguments

Applicant, in the Reply entered 8/30/2007, traverse that the provisional rejection for obvious-type double patenting over copending Serial No. 10/244,727, and state that "[w]hen the claims are otherwise in condition for allowance, Applicants will file a terminal disclaimer, if appropriate." Applicant has not addressed the provisional obviousness-type double patenting rejections over 10/813,612 (claims 1-9); 10/934,977 (claims 1-9); 11/004,593 (claims 25-32); 11/217,384 (claims 1-6); and 11/223,463 (claims 1 and 2).

Applicant's arguments, entered 8/30/2007, have been fully considered but they are not persuasive. Applicant's arguments do not substantively traverse the aforementioned rejections under provisional obviousness-type double patenting. Therefore the rejections over copending applications 10/244,727, 10/813,612 (claims 1-9); 10/934,977 (claims 1-9); 11/004,593 (claims 25-32); 11/217,384 (claims 1-6); and 11/223,463 (claims 1 and 2), are maintained.

Conclusion

21. Claims 78-82, 84-86, 88-91 stand finally rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya, whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Doug Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1639